

01241.000015

PATENT APPLICATION



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor Application of:

MASANOBU HOKASE

Application No.: 09/581,758

Filed: June 16, 2000

For: METHODS FOR PREVENTING  
AND TREATING MASTITIS

) Examiner: Michael V. Meller

) Group Art Unit: 1651

) March 26, 2003

Assistant Commissioner for Patents  
Washington, D.C. 20231

SUBMISSION OF ORIGINAL DECLARATION

Sir:

Applicants submit herewith an executed original Declaration of Dr. Ryoji Onodera to be placed of record in the above-identified application.

REMARKS

Dr. Onodera is a Doctor of Agriculture and a professor in the Faculty of Agriculture at Miyazaki University. Dr. Onodera has received numerous professional awards and honors, including in 2001 the Prize of Association of Japanese Agricultural Scientific Society.

In the enclosed Declaration, Dr. Onodera explains the etiology of mastitis and the correlation of body cell count ("BCC") e.g., the number of leukocytes and tissue cells in bulk milk (milk pooled from several contributing cows) as an art-recognized universal indicator of the onset of mastitis in individual cows contributing to that milk. Cows contributing to bulk milk with BCC of less than 200,000/ml are recognized by those

1651  
#18  
[Signature]

RECEIVED  
MAR 31 2003  
TECH CENTER 1600/2900

of ordinary skill to be healthy, those of ordinary skill recognize that the cows contributing bulk milk with more than 500,000/ml BCC are statistically probable (with high degree of confidence) to have mastitis, and for bulk milk with BCC between 200,000-500,000, it is statistically probable (with high degree of confidence) are developing mastitis<sup>1/</sup>

Dr. Onodera explains the import and showings in the Examples in the specification involving bulk milk with BCC of 250,000/ml, e.g., samples for which contributing cows are actively developing mastitis. As discussed in detail, Example 1 shows that the BCC of bulk milk decreases from developing mastitis levels to healthy levels when contributing cows are fed phytase. Example 2 is similar and absolutely demonstrates contributing cows are actually prevented from developing mastitis (cows in the control group developed mastitis and had to be removed from the study), Example 7 shows the reproduceability of this result and Example 3 shows phytase is more effective than the art-accepted treatment of zinc methionate.

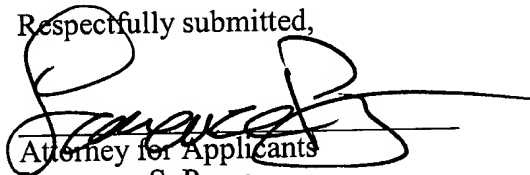
Entry hereof and early allowance of this application are respectfully requested.

---

<sup>1/</sup> See <http://www.ianr/unl.edu/pubs/dairy/g1151.htm>,  
<http://www.moomilk.com/archive/u-health-20.htm> and  
<http://www.nmconline.org/articles/sccprimer.pdf>.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should be directed to our below listed address.

Respectfully submitted,



Attorney for Applicants  
Lawrence S. Perry  
Registration No. 31,865

FITZPATRICK, CELLA, HARPER & SCINTO  
30 Rockefeller Plaza  
New York, New York 10112-3801  
Facsimile: (212) 218-2200

LSP\ac

NY\_MAIN 333883v1